

MAY 28 2002

## 510(k) Summary

### Anzai eZ-Scope AN Portable Gamma Camera

Common/Classification Name: Gamma Camera, 21 CFR 892.1100

Anzai Medical Company, Ltd.  
3-6-25 Nishi-Shinagawa  
Shinagawa-ku  
Tokyo 141-0033  
Japan

Contact: Masao Jimbo, Prepared: May 10, 2002

#### A. LEGALLY MARKETED PREDICATE DEVICES

The **eZ-Scope AN Portable Gamma Camera** is substantially equivalent to the Notebook Imager made by Digirad, which was cleared by FDA on May 28, 1997 as K961004. For some characteristics, it is also substantially equivalent to the Siemens E.CAM gamma camera (K992731) and the Neoprobe 2000 Isotope Probe (based on K971320 for the Neo 1500).

#### B. DEVICE DESCRIPTION

The **Anzai eZ-Scope AN Portable Gamma Camera** is a new and innovative portable gamma camera. The camera utilizes a solid state detector, rather than a scintillator, to detect gamma rays. The cadmium-zinc-tellurium detector allows sharp energy discrimination and spatial resolution.

The detector array is made from pixelized cadmium-zinc-telluride (CZT) crystals, with each of the 256 pixels having dimensions of 2 x 2 mm.

The system will be available in two configurations, **eZ-Scope AN** and **eZ-Scope Lite**. These differ primarily in the computer, the former model using a desktop computer and the latter a laptop. In the desktop version, the computer is mounted on a cart, while the laptop version does not have a cart.

#### C. INTENDED USE

The **Anzai eZ-Scope AN Portable Gamma Camera** is indicated for use to image the distribution of radionuclides in the human body using planar imaging techniques. The **eZ-Scope** may be used on pathological specimens if a protective sheath is used.

#### **D. SUBSTANTIAL EQUIVALENCE SUMMARY**

The **eZ-Scope** is a medical device, and it has similar indications for use and target population as the legally marketed predicate devices. However, the differences in indications for use do not affect the intended diagnostic effect. The **eZ-Scope** has the same technological characteristics as the predicate devices. For most characteristics, this premarket notification will describe the characteristics of the **eZ-Scope** in sufficient detail to assure substantial equivalence.<sup>1</sup> For a few characteristics, performance data are provided to assure equivalence.

#### **E. TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics are the same as those of the predicate devices.

#### **F. TESTING**

Performance testing addressed the following issues:

- (1) Electrical Safety;
- (2) Electromagnetic Compatibility;
- (3) NEMA Performance Standard; and
- (4) Sample Clinical Images

#### **G. CONCLUSIONS**

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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<sup>1</sup> The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.



MAY 28 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

T. Whit Athey, Ph.D.  
Senior Consultant  
Health Policy Resources Group  
2305 Gold Mine Road  
BROOKVILLE MD 20833

Re: K020643  
Trade/Device Name: EZ-Scope AN & EZ-Scope AN Lite  
Portable Gamma Camera  
Regulation Number: 21 CFR 892.1100  
Regulation Name: Scintillation (gamma) camera  
Regulatory Class: I  
Product Code: 90 IYX  
Dated: February 27, 2002  
Received: February 27, 2002

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

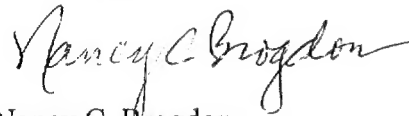
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K020643

Device Name: Anzai eZ-Scope Portable Gamma Camera

Indications For Use:

The Anzai eZ-Scope AN Portable Gamma Camera is indicated for use to image the distribution of radionuclides in the human body using planar imaging techniques. The eZ-Scope may be used on pathological specimens if a protective sheath is used.

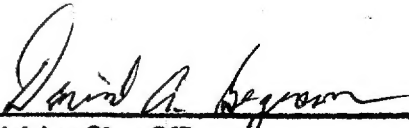
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K020643